

§ 524.1484e

equivalent to 3.5 milligrams of neomycin base, 5 milligrams of hydrocortisone acetate, and 5 milligrams of tetracaine hydrochloride in each gram of ointment.

(b) *Sponsor*. See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs and cats*—

(1) *Amount*. Instill a quantity of ointment sufficient to fill the external ear canal; may be applied one to three times daily.

(2) *Indications for use*. For the treatment of ear canker and other inflammatory conditions of the external ear canal, acute otitis externa and, to a lesser degree, chronic otitis externa.

(3) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 13873, Mar. 27, 1975, as amended at 49 FR 21922, May 24, 1984; 79 FR 10970, Feb. 27, 2014]

§ 524.1484e Neomycin and polymyxin B ophthalmic solution.

(a) *Specifications*. Each milliliter of the ophthalmic preparation contains 5.0 milligrams neomycin sulfate (3.5 milligrams neomycin base), and 10,000 Units of polymyxin B sulfate.

(b) *Sponsor*. See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount*. Instill 1 to 2 drops per eye every 6 hours.

(2) *Indications for use*. For the treatment of bacterial infections associated with topical ophthalmological conditions such as corneal injuries, superficial keratitis, conjunctivitis, keratoconjunctivitis, and blepharitis.

(3) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 13873, Mar. 27, 1975, as amended at 61 FR 5507, Feb. 13, 1996; 79 FR 10970, Feb. 27, 2014]

§ 524.1484f Neomycin, prednisolone, and tetracaine otic suspension.

(a) *Specifications*. The product contains 5 milligrams of neomycin sulfate equivalent to 3.5 milligrams of neomycin base, 2.5 milligrams of prednisolone acetate, and 5 milligrams of tetracaine hydrochloride in each milliliter of sterile suspension.

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(b) *Sponsor*. See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs and cats*—

(1) *Amount*. Instill 2 to 6 drops in the external ear canal 2 or 3 times daily.

(2) *Indications for use*. For the treatment of acute otitis externa and, to a lesser degree, chronic otitis externa; as treatment or adjunctive therapy of certain ear conditions caused by or associated with neomycin-susceptible organisms and/or allergy.

(3) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 13873, Mar. 27, 1975, as amended at 79 FR 10971, Feb. 27, 2014]

§ 524.1484g Neomycin, thiabendazole, and dexamethasone solution.

(a) *Specifications*. Each cubic centimeter of neomycin sulfate-thiabendazole-dexamethasone solution contains: 40 milligrams of thiabendazole, 3.2 milligrams of neomycin (from neomycin sulfate), and 1 milligram of dexamethasone.

(b) *Sponsor*. See No. 050604 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs and cats*—

(1) *Amount*. In treating dermatoses affecting areas other than the ear, the surface of the lesions should be well moistened (2 to 4 drops per square inch) twice daily. In treating otitis externa, instill 5 to 15 drops in the ear twice daily. Treat for up to 7 days.

(2) *Indications for use*. As an aid in the treatment of bacterial, mycotic, and inflammatory dermatoses and otitis externa.

(3) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 13873, Mar. 27, 1975, as amended at 62 FR 63271, Nov. 28, 1997; 79 FR 10971, Feb. 27, 2014]

§ 524.1484h Neomycin, penicillin, polymyxin B, and hydrocortisone suspension.

(a) *Specifications*. Each milliliter of suspension contains 25 milligrams of neomycin sulfate equivalent to 17.5 milligrams of neomycin, 10,000 international units of penicillin G procaine, 5,000 international units of polymyxin

B sulfate, 2 milligrams of hydrocortisone acetate, and 1.25 milligrams of hydrocortisone sodium succinate.

(b) *Sponsor*. See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount*. Rub a small amount into the affected area 1 to 3 times a day. After definite improvement, apply once daily or every other day.

(2) *Indications for use*. For the treatment of summer eczema, atopic dermatitis, interdigital eczema, and otitis externa caused by bacteria susceptible to neomycin, penicillin, and polymyxin B.

(3) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(d) *Conditions of use—dogs*—(1) *Amount*. Rub a small amount into the involved area 1 to 3 times a day. After definite improvement, it may be applied once a day or every other day.

(2) *Indications for use*. Treatment of summer eczema, atopic dermatitis, interdigital eczema, and otitis externa caused by bacteria susceptible to neomycin, penicillin, and polymyxin B.

(3) *Limitations*. For use in dogs only. Shake drug thoroughly and clean lesion before using. If redness, irritation, or swelling persists or increases, discontinue use and reevaluate diagnosis. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[59 FR 5105, Feb. 3, 1994, as amended at 79 FR 10971, Feb. 27, 2014]

§ 524.1484i Neomycin and hydrocortisone ointment.

(a) *Specifications*. The drug contains 5 milligrams of neomycin sulfate, equivalent to 3.5 milligrams of neomycin base, and 5 milligrams of hydrocortisone acetate in each gram of ointment.¹

(b) *Sponsor*. See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs and cats*—(1) *Amount*. Apply 3 or 4 times daily into the conjunctival sac. With improvement, frequency may be reduced to 2 or 3 times daily. For treatment of ear canker and other inflammatory conditions of the external ear canal, fill external ear canal 1 to 3 times daily.

(2) *Indications for use*. For the treatment of infections, allergic and traumatic keratitis, conjunctivitis, acute otitis externa and, to a lesser degree, chronic otitis externa.

(3) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[43 FR 40456, Sept. 12, 1978, as amended at 79 FR 10971, Feb. 27, 2014]

§ 524.1484j Neomycin and prednisolone ophthalmic ointment.

(a) *Specifications*. Each gram of ointment contains prednisolone sodium phosphate equivalent to 2.5 milligrams prednisolone 21-phosphate and 5 milligrams neomycin sulfate equivalent to 3.5 milligrams neomycin base.

(b) *Sponsor*. See No. 050604 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs and cats*—(1) *Amount*. A small quantity of the ointment should be expressed into the conjunctival sac 4 times a day (at intervals of 1 to 8 hours) for a few days until there is a favorable response, then the frequency of application may be reduced to twice daily as long as the condition remains under control. Treatment may require from a few days to several weeks.

(2) *Indications for use*. For use in superficial ocular inflammations or infections limited to the conjunctiva or the anterior segment of the eye, such as those associated with allergic reactions or gross irritants.

(3) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 10971, Feb. 27, 2014]

§ 524.1484k Prednisolone and neomycin suspension.

(a) *Specifications*. Each milliliter of suspension contains 2.5 milligrams of prednisolone acetate and 5 milligrams of neomycin sulfate equivalent to 3.5 milligrams of neomycin base.

(b) *Sponsor*. See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs and cats*—(1) *Amount*. For beginning treatment of acute ocular inflammations place 1 or 2 drops in the conjunctival sac 3 to 6 times during a 24 hour period. When improvement occurs, reduce the dosage